K121999

Dräger

510(k) Summary acc. to 21 CFR 807.92

Applicants Name and Address:

FEB 28 2013

Dräger Medical GmbH
Moislinger Allee 53-55
23542 Lübeck
Germany

Manufacturer Name and Address:

Dräger Medical GmbH
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number :

9611500

Contact Person:

Ulrich Schröder
Director Regulatory Affairs & Clinical Affairs

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Applicants US Contact Person

Beth Zis
Director Regulatory Affairs

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Date submission was prepared:

2012/07/06

Device Name:

Common Name:	Temperature Probes (General Purpose/ Skin)
Classification Name:	Clinical electronic thermometer, FLL
Regulation Number:	21 CFR 880.2910
Class:	II

Legally Marketed Devices to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K946306	SC 9000 Bedside Monitor, SC 9015 Bedside Monitoring System	Dräger (former Siemens)
K050837	Reusable temperature probes (Skin Temperature Probe, reusable; General Purpose Temperature Probe, reusable	GE HEALTHCARE
K051873	Disposable temperature, Skin and Oesophageal probes	GE HEALTHCARE
K070339	Disposable temperature probes/ sensors and instrument cables	CINCINNATI SUB-ZERO PRODUCTS, INC

Device Description:

Temperature probes are used during patient temperature measurement and consist of a plug connected to a patient monitor and a thermistor on the patient end. The thermistor consists of a resistor which is sensitive to temperature changes. The portfolio includes General Purpose Temperature probes to be inserted into the oesophagus or the rectum and Skin Temperature Probes.
The devices are intended for single patient use and can be used with Dräger and Siemens patient monitors.

Intended Use:

General Purpose Temperature Probes

Dräger disposable general purpose temperature probes are intended for patient core body temperature measurement in combination with Dräger and Siemens patient monitoring systems. The probes are inserted into the oesophagus or the rectum.

Skin Temperature Probes

Dräger disposable skin temperature probes are intended for patient skin temperature measurement in combination with Dräger and Siemens patient monitoring systems. The probes are affixed on the patient's skin with an adhesive cover.

Verification & validation measures include but are not limited to the following key tests: Shock & Vibration, Storage and Transport, Compatibility to devices, Accuracy Test, Electrical Safety, Biocompatibility, Mechanical tests (bending, connection cycles, pull-off forces) Labelling review, Resistance to fluids and disinfectants, Shelf Life.

Differences, Similarities and Conclusion:

The Dräger temperature probes are identical in fit, form and function to the predicates. The intended use and general construction as the predicate devices remain the same. The function and principle of operation as well as the characteristic of the used NTC (YSI400) are equal.

The Dräger temperature probes are non-sterile and are intended for single patient use instead of some predicates. The Dräger temperature probes use different materials but the devices are made from biocompatible materials and all verification and validation data provided indicate product performance is given within the range the device can be used by clinicians. In summary, the disposable temperature probes described in this submission are substantially equivalent to the predicate devices.

NTC-Negative Temperature Coefficient Thermistor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Draeger Medical GmbH
C/O Ms. Beth Zis
Director, Regulatory Affairs
Draeger Medical Systems, Incorporated
6 Tech Drive
ANDOVER MA 01810

Re: K121999
Trade/Device Name: General Purpose Temperature Probes, Skin Temperature Probes
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 31, 2013
Received: February 4, 2013

Dear Ms. Zis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	K121999
Device Name	*General Purpose Temperature Probes* *Skin Temperature Probes*
Indications for Use	*General Purpose Temperature probes* Dräger disposable general purpose temperature probes are intended for patient core body temperature measurement in combination with Dräger and Siemens patient monitoring systems. The probes are inserted into the oesophagus or the rectum. *Skin Temperature probes* Dräger disposable skin temperature probes are intended for patient skin temperature measurement in combination with Dräger and Siemens patient monitoring systems. The probes are affixed on the patient's skin with an adhesive cover.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ (Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

FDA

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121999